DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 12,2014

Mr. Patrick Lim
Manager
HIOSSEN, Incorporated
85 Ben Fairless Drive
Fairless Hills, PA 19030

Re: K140934
Trade/Device Name: HIOSSEN Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: October 6, 2014
Received: October 10, 2014

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Hiossen Inc.
85 Ben Fairless Dr. Fairless Hills, PA 19030
Tel : 1-888-678-0001 / Fax : 1-267-759-7004
www.hiossen.com

Indications for Use Statement

510(k) Number K K140934

Device Name : HIOSSEN Implant System

Indication for use :
The HIOSSEN Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. ETIII SA Ultra Wide Fixture is intended to be used in the molar region.

Prescription Use X (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Hiossen Inc.
85 Ben Fairless Dr. Fairless Hills, PA 19030
Tel : 1-888-678-0001 / Fax : 1-267-759-7004
www.hiossen.com

K140934

510(k) Summary

This summary of 510(k) substantial equivalence information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date : November 15, 2013

1. Company and Correspondent making the submission:

- Submitter's Name :	HiOSSEN Inc.
- Address :	85 Ben Fairless Dr. Fairless Hills PA 19030
- Telephone No.	888 678 0001
- Contact :	Mr. Patrick Lim

2. Device :

Trade or (Proprietary) Name :	HIOSSEN Implant System
Common or usual name :	Dental Implant
Classification Name :	Endosseous Dental Implant 21CFR872.3640 Class II DZE, NHA

3. Predicate Device :
HT III SA FIXTURE SYSTEM, HIOSSEN Inc, K101096
ETII SA Fixture System, HiOSSEN Inc., K123471
ETIII SA Ultra Wide System, HiOSSEN Inc., K103537
TS Implant System, OSSTEM CO., LTD., K121585
HSII Short Fixture System, OSSTEM CO., LTD., K083633
ET SS Implant System, OSSTEM CO., LTD., K120847
3i OSSEOTITE® Certain® Dental Implants, Implant Innovations, Inc., K063341

4. Description :

1) The HIOSSEN Implant System is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

2) The HIOSSEN Implant System include length 18mm implant
Length 18mm implant has already predicated in K063341, 3i OSSEOTITE® Certain® Dental Implants(Length 7mm~20mm)

Hiossen Inc.
85 Ben Fairless Dr. Fairless Hills, PA 19030
Tel : 1-888-678-0001 / Fax : 1-267-759-7004
www.hiossen.com

3) ETIII SA Fixture

Device Description	Intended to be surgically placed in the bone of the upper or lower jaw arches. Fixture is supplied sterile.		
Material	Pure Titanium (ASTM F 67)		
Surface	SA surface treatment		
	Diameter (mm)	Length (mm)	added/modified
Dimension	3.77	8.7	Diameter is modified
	3.75	10.2, 11.7, 13.2, 15.2, 18.2	Length 18.2mm is added
	4.25	7.2, 8.7, 10.2, 11.7, 13.2, 15.2, 18.2	Length 18.2mm is added
	4.65	7.2	None
	4.63	8.7	Diameter is modified
	4.6	10.2, 11.7, 13.2, 15.2, 18.2	Length 18.2mm is added
	5.1	6.2, 7.2	Length 6.2mm is added
	5.08	8.7	None
	5.05	10.2, 11.7, 13.2, 15.2	None

4) ETIII SA Ultra-Wide Fixture

Device Description	Intended to be surgically placed in the bone of the upper or lower jaw arches. Fixture is supplied sterile.		
Material	Pure Titanium (ASTM F 67)		
Surface	SA surface treatment		
	Diameter (mm)	Length (mm)	added/modified
Dimension	5.95	6.2, 9.7	Diameter is modified/ Length 6.2mm is added
	5.92	11.2, 12.7	Diameter is modified
	6	7.2, 8.2	None
	6.8	6.2, 7.2, 8.2, 9.7, 11.2, 12.7	Diameter is modified/ Length 6.2mm is added

5) ETII SA Fixture

Device Description	Intended to be surgically placed in the bone of the upper or lower jaw arches. Fixture is supplied sterile.		
Material	Pure Titanium (ASTM F 67)		
Surface	SA surface treatment		
	Diameter (mm)	Length (mm)	added/modified
Dimension	3.5	8.7, 10.2, 11.7, 13.2, 15.2, 18.2	Length 18.2mm is added
	4.2	7.2, 8.7, 10.2, 11.7, 13.2, 15.2, 18.2	Length 18.2mm is added
	4.45	7.2, 8.7, 10.2, 11.7, 13.2, 15.2	None
	5.0	6.2	None
	4.9	7.2, 8.7, 10.2, 11.7, 13.2, 15.2	None

Hiossen Inc.
85 Ben Fairless Dr. Fairless Hills, PA 19030
Tel : 1-888-678-0001 / Fax : 1-267-759-7004
www.hiossen.com

6) Cover Screw

Device Description	Used to protect the exposed platform of the implant during healing period.
Material	Pure Titanium (ASTM F 67)
Surface	Anodizing
diameters	3.03, 3.58, 3.25, 3.4, 3.75, 3.9
lengths	5.25, 5.9, 6.25, 6.85, 6.9, 7.5
Change content as compared to the predicate device	Products code, Art(#)s are changed & Design Change of screw bottom

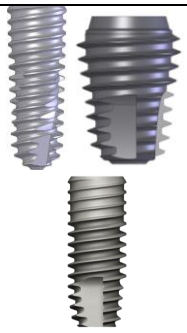
7) Healing Abutment

Device Description	Used to make a soft tissue in a funnel shape before setting up prosthetics and removing cover screw after osseointegration.
Material	Pure Titanium (ASTM F 67)
Surface	None
diameters	4.3, 4.8, 5.3, 6.3, 7.3
lengths	7.5, 8.5, 9.5, 11.5, 12.5
Change content as compared to the predicate device	Addition of ø4.5mm abutment. Shape of middle part is changed

- Substantial Equivalence Matrix

	The HIOSSEN Implant System	**Predicate devices**	
		HTIII SA Fixture / ETIII SA Ultra Wide System	**ETII SA Fixture System**
510(K) No.	-	K101096 / K103537	K123471
Manufacturer	HIOSSEN Inc.	HIOSSEN Inc.	HIOSSEN Inc.

Hiossen Inc.
85 Ben Fairless Dr. Fairless Hills, PA 19030
Tel : 1-888-678-0001 / Fax : 1-267-759-7004
www.hiossen.com

Design			
Intended Use	The HIOSSEN Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. ETIII SA Ultra-Wide Fixture is intended to be used in the molar region.	The HTIII Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide Fixture System is intended to be used in the molar region.	The ETII Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.
Structure	- Internal Hex-connected - Submerged Fixture - Tapered body shape & Straight body shape	- Internal Hex-connected - Submerged Fixture - Tapered body shape & Straight body shape	- Internal Hex-connected - Submerged Fixture - Straight body shape
Diameter (D)	3.5, 3.75, 3.77, 4.2, 4.25, 4.45, 4.6, 4.25, 4.63, 4.65, 4.9, 5.0, 5.05, 5.08, 5.1, 5.92, 5.95, 6, 6.8	3.75, 4.25, 4.6, 5.05, 5.08, 5.1, 6, 5.92, 5.95, 6.8, 6.82	3.5, 4.2, 4.45, 4.9, 5.0
Length (mm)	6.2, 7.2, 8.7, 10.2, 11.7, 13.2, 15.2, 18.2	7.2, 8.7, 10.2, 11.7, 13.2, 15.2	6.2, 7.2, 8.7, 10.2, 11.7, 13.2, 15.2
Material of Fixture	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Surface	SA	SA	SA
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
Shelf life	8 Years	5 Years	5 Years

Hiossen Inc.
85 Ben Fairless Dr. Fairless Hills, PA 19030
Tel : 1-888-678-0001 / Fax : 1-267-759-7004
www.hiossen.com

S E	The HIOSSEN Implant System is revised product that Dimension and code(art#) are changed and added from predicate product, ETII SA Fixture, HTIII SA Fixture and ETIII SA Ultra Wide Fixture therefore there is no difference about material, indication for use and design from predicate as above And the subject devices and the predicate devices encompass the same range of physical dimensions except length 18mm and characteristics, including implant diameter and surface treatment therefore The HIOSSEN Implant System is substantially equivalent to the predicate devices

5. Indication for use :
The HIOSSEN Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. ETIII SA Ultra-Wide Fixture is intended to be used in the molar region.

6. Review :
The HIOSSEN Implant System has same material, indication for use, similar design and technological characteristics as the predicate device.

7. Summary of nonclinical testing
Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence includes engineering analysis**,** dimensional analysis, static and dynamic compression-bending testing according to "Guidance for industry and FDA staff Class Ⅱ Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" with the worst case scenario. Fatigue testing in air demonstrated the subject device to be equivalent to the tested predicate because shape and minimum diameter of subject devices are the same with predicate.

8. Summary of clinical testing
No clinical studies are submitted

9. Conclusions
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807**,** and based on the information provided in this premarket notification HiOSSEN Inc. concludes that the The HIOSSEN Implant System is substantially equivalent to the predicate devices as described herein